

11/12/04 11:10 - 11:10

By Federal Express

November 29, 2004

Division of Dockets Management (HFA-305)  
U.S. Food and Drug Administration (FDA)  
5630 Fishers Lane Room 1061  
Rockville, MD 20852

Re: Docket No. 2004N-0432

Dear Sir or Madam:

On behalf of the Society of Nuclear Medicine (SNM), I write to express our organization's concern over the January 16, 2005 deadline for comments in connection with the November 16, 2004 RDRC meeting at FDA headquarters on "Radioactive Drugs for Certain Research Uses."

As both a presenter and representative on behalf of SNM at the November 16 RDRC meeting, I and other participants that day were made aware that the FDA expects to issue a "Screening IND Guidance Draft" within the same January 16 timeframe as comments are due. It is our further understanding that this Screening IND Guidance Draft document may materially affect the RDRC issues under discussion and for which comments are currently required by January 16, 2005.

Because of the potential material affect of the Screening IND Guidance Draft document on our RDRC comments, SNM believes that the January 16, 2005 deadline for comments should prudently be extended for a period of at least six to eight weeks from the date on which the Guidance is actually released.

Thank you in advance in for your consideration. With best regards,

Sincerely,



Mathew L. Thakur, Ph.D.  
President

cc: George Mills, M.D. – CDER

2004N-0432

EXT 2